K132887

DEC 20 2013

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared	September 16th, 2013
Owner's Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
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Official Contact	Mr. Jim Cassi Vice President - Quality Assurance Americas ResMed Corp. 9001 Spectrum Center Blvd San Diego CA 92123 USA **Tel:** +1 858 836 6081 **Fax:** +1 858 836 5519 jim.cassi@resmed.com.au
Device Trade Name	AirFit™ N10
Device Common Name	Vented Nasal Mask
Classification & Classification Name	21 CFR 868.5905, 73 BZD (Class II) Noncontinuous Ventilator (IPPB)
Legally Marketed Predicate Devices	Swift FX Nano (K123789) Ultra Mirage II (K050359) SleepNet Mojo (K060273)
Intended Use	The AirFit™ N10 channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device. The AirFit™ N10 is: • to be used by patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed • intended for single-patient re-use in the home environment and multipatient re-use in the hospital / institutional environment.
Reason for Submission	New Device
Device Description	The AirFit™ N10 is an externally worn mask that provides an air seal, such that air flow from a positive pressure source is directed to the patient's nose. The mask is held in place with an adjustable headgear. It connects to a conventional PAP device air delivery hose via a standard 22mm swivel. The mask may be cleaned with mild soap. An exhaust vent port is incorporated into the frame to provide a

continuous air leak to prevent rebreathing of dead space CO_2. **AirFit™ N10** is a prescription device supplied non-sterile.

Intended Use comparison

Comparison with predicate Swift FX Nano (K123789)
The new device and the predicate Swift FX Nano mask have identical intended uses. Both are intended to be used with Positive Air Pressure therapy equipment and for the same identical patient population.

Technological Characteristics comparison

Comparison with predicate Swift™ FX Nano (K123789)
Similarities:
The new device and the predicate mask, provide a seal via a silicone interface. Both devices incorporate a silicone cushion that seals around the patient's nose. Both masks are offered in multiple sizes to ensure adequate fit over the extended patient population.

Both masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard 22mm conical connectors (ref: ISO 5356-1:2004).

Both masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the components of both masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

In addition, development of the **AirFit™ N10** device complies with ISO 14971:2007, Medical devices - Application of risk management to medical devices.

Both the new mask and the predicate device are designed to operate on the same *Pillows*, *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both devices are identical.

Both the new mask and the predicate device can be reused in the home and hospital / institution environment.

The main *differences* with the new device are:
(a) The headgear fixes to the mask at 4 attachment points.
(b) Magnets are incorporated in the headgear clip design to improve usability.
(c) Mask reassembly is made simpler through parts integration.
(d) The exhaust port design is of a diffused vent type.

Comparison with predicate SleepNet Mojo (K060273)
Both devices incorporate magnets in the headgear clip design. The clips are self-locating and they also provide audible and tactile feedback to indicate successful mechanical engagement.

Non-clinical testing and performance data comparison

The CO_2 washout performance of the new device was tested to ensure the mask design provides adequate venting to flush out the expired CO_2. The testing included physical and functional dead-space measurements. The device satisfied all predefined pass/fail criteria and was shown to be substantially equivalent to

the predicate Ultra Mirage II device (K050359).

Pressure-flow and through impedance bench test results of the new mask were also substantially equivalent to the predicate Swift FX Nano device (K123789).

Mechanical integrity performance of the new device was tested to simulated normal use and reasonable abuse scenarios. The device was also tested to demonstrate that it can withstand the effects of storage temperature, humidity and transportation shock & vibration.

Validation of cleaning and reuse was completed to establish that the device can be safely reused by a single patient, or multipatient reuse in the hospital/institutional environment following validated disinfection protocols. After 20 cycles of cleaning/disinfection in accordance with the methods described in the cleaning / disinfection guide, the device has been shown to function as intended. The device satisfied the pass/fail criteria and was shown to be substantially equivalent to the predicate devices.

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent "external communicating devices" (with tissue/bone/dentin). The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1 were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity,
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization.

The appropriate biological tests conducted and passed for components considered to be in permanent skin contact, in accordance with FDA guidance #G95-1, were:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization and Irritation

Clinical Data

Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Clinical data was not relied upon to demonstrate Substantial Equivalence to predicate devices. Bench testing alone is sufficient.

Substantial Equivalence Conclusion

The new AirFit™ N10 is as safe and effective as the predicate devices:

- it has the same intended use;
- it has identical technological characteristics to the predicate devices;
- the new device did not raise any new questions of safety or effectiveness;
- it is at least as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

ResMed Limited
Mr. Jim Cassi
Vice President – Quality Assurance Americas
9001 Spectrum Center Boulevard
SAN DIEGO CA 92123

Re: K132887
Trade/Device Name: AirFit N10™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous Ventilator (Respirator)
Regulatory Class: Class II
Product Code: BZD
Dated: November 15, 2013
Received: November 18, 2013

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K132887
Device Name: AirFit™ N10
Indication for Use

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Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S
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